IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	**Redacted - Public Version** C.A. No. 22-252-JDW **JURY TRIAL DEMANDED**
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Counterclaim- Defendants.*	[redacted]

PLAINTIFFS' RESPONSIVE BRIEF IN OPPOSITION TO MODERNA'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT

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Judicial reassignments are ministerial adjustments of the Court's docket, not invitations to whitewash prior adjudications. Moderna seeks summary judgment as to certain government sales and infringement under the doctrine of equivalents without acknowledging, much less engaging with, Chief Judge Goldberg's rulings that doom its motion. The Court's prior denial of Moderna's partial motion to dismiss properly interpreted § 1498 in a manner that mandates denial of Moderna's motion and entry of summary judgment for Plaintiffs. Moderna provides no basis to reverse the Court's prior, and correct, interpretation of the governing case law.

Likewise, Moderna's summary judgment motion on the doctrine of equivalents urges an interpretation of the prosecution history that defies this Court's prior determination that Plaintiffs did *not* disclaim all values beyond the numerical ranges recited by the claims. Moderna again treats summary judgment as a mulligan, this time for a *Markman* decision that forecloses its theory.

Finally, Moderna's indefiniteness argument ignores the facts and the law. Controlling law dictates that alleged difficulty in testing for infringement—the basis for Moderna's motion—cannot render claims indefinite where, as both parties' experts agree here, the claim scope is understood. Evidence that its summary judgment motion never addresses, from both Plaintiffs' and Moderna's witnesses and documents, reflects that "fully encapsulated" was a well-understood term, and that standard measurements could assess infringement, requiring denial of Moderna's motion. Summary judgment on indefiniteness is thus appropriate, but only for Plaintiffs.

II. ARGUMENT

A. The Court Should Grant Summary Judgment for Plaintiffs on Moderna's Section 1498 Affirmative Defense.

> *We are a nation that has a government—not the other way around.*
> –Ronald Reagan, First Inaugural Address (January 20, 1981)

American taxpayers gave Moderna billions of dollars, enriching its executives and funding

the research, clinical trials, and manufacture of its first commercial product: the COVID-19 vaccine. The U.S. Government purchased hundreds of millions of vaccine doses, which were provided to local governments and pharmacies. The purchase was not "for the Government;" it was for millions of Americans who received those doses and gained protection against the virus.

Moderna, however, wants to leave the American taxpayer with the tab for its infringement. It points to 28 U.S.C. § 1498(a), a World War I-era statute to encourage military contractors to provide materials for the war effort. *Zoltek Corp. v. United States*, 672 F.3d 1309, 1315 (Fed. Cir. 2012). The statute waives sovereign immunity and imposes Government liability for a contractor's patent infringement that is (1) "for the Government" and (2) occurs "with the authorization or consent of the Government." 28 U.S.C. § 1498(a); *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014). Section 1498 is an affirmative defense, *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1381 (Fed. Cir. 2002), and thus Moderna bears the burden as to both prongs.

Pursuant to the Court's Order, D.I. 485 ¶ 4, Plaintiffs both oppose Moderna's motion and cross-move for summary judgment with respect to § 1498. *See Transportes Ferreos de Venezuela II CA v. NKK Corp.*, 239 F.3d 555, 560 (3d Cir. 2001) (cross motions are "not an agreement that if one [motion] is rejected the other is necessarily justified"). No court ever has adopted Moderna's expansive reading of § 1498, which could shift liability whenever the Government contracts for goods or services for the public's benefit. As this Court correctly recognized in rejecting Moderna's motion to dismiss, § 1498(a) applies only to infringing articles that are "for the Government." D.I. 64 at 3. Text, history, precedent, and common sense all indicate that phrase means articles used by the Federal Government for its own activities. Here, by contrast, the vast majority of doses were provided to third parties, including state and local governments and private pharmacies. Further, all doses sold under the C-100 contract are accused of indirect infringement,

which § 1498 does not shield. Even if the Court disagrees, there are genuine factual disputes with respect to authorization and consent—namely, the considerable evidence that Moderna obtained the C-100 contract by lying to the Government about its infringement of the Asserted Patents. Those factual disputes preclude the entry of summary judgment for Moderna.

1. Section 1498 does not apply to vaccine purchases for the general public.

a. Moderna's attempt to collapse the inquiry is atextual and contrary to Federal Circuit precedent.

Moderna's motion begins with a brazen effort to avoid the test laid out in statute and Federal Circuit precedent, rehashing the same argument Chief Judge Goldberg rejected in this case: that the Government, rather than the Court, decides whether the "for the Government" prong of the statute is met. D.I. 64 at 3. This Court held that "a governmental grant of authorization or consent, standing alone, does not mean that the alleged use or manufacture is done 'for the United States' under § 1498(a)." D.I. 31 at 9 (quoting *IRIS*, 769 F.3d at 1362)). Nothing has changed.

Collapsing the inquiry into a single element contravenes the plain text of the statute, which only waives sovereign immunity for a contractor's "use or manufacture of an invention" if that use or manufacture is done both "for the Government ***and*** with the authorization or consent of the Government." 28 U.S.C. § 1498(a).[1] "[E]very word and every provision [in a statute] is to be given effect." *Nielsen v. Preap*, 586 U.S. 392, 414 (2019). If Congress intended express authorization and consent on its own to be sufficient, it would have said so. *See Gallardo ex rel. Vassallo v. Marstiller*, 596 U.S. 420, 429 (2022) ("If Congress had intended to draw such a distinction, it easily could have drafted language to that effect."). Moreover, because the statute is a waiver of sovereign immunity, "[a]ny ambiguity in [§ 1498] must be resolved in favor of

[1] Unless otherwise noted, all emphasis is added, and internal citations and quotations are omitted, throughout the brief. Exhibits to the Decls. of Matthew W. Lachman are cited as "Ex". Moderna's exhibits are referred to as "M. Ex." The Affirmative Statement of Facts is cited as "ASOF."

immunity," *Zoltek*, 672 F.3d at 1318, rather than the expanded scope Moderna advances.

The Federal Circuit repeatedly has held that § 1498 requires proof that the infringement was both (i) "for the Government" and (ii) with the "authorization or consent" of the Government. *IRIS*, 769 F.3d at 1362; *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1376 (Fed. Cir. 2009). Indeed, the very case Moderna cites to justify bypassing the "for the Government" prong held that a contractor is only "immune from suit . . . if ***two criteria*** are met: (1) the use is 'for the Government'; ***and*** (2) the use is 'with the authorization and consent of the Government.'" *Sevenson Env't Servs., Inc. v. Shaw Env't*, 477 F.3d 1361, 1365 (Fed. Cir. 2007).

In *Sevenson*, the infringement involved remediating waste on land owned and managed by the Federal Government. *Id.* at 1363. There was thus no dispute that the Government both received and was the direct beneficiary of the infringing activity. *Sevenson* explained that where courts have "bypassed a separate inquiry into whether infringing activity was performed 'for the Government,'" they have done so only "where infringing activity has been performed by a government contractor pursuant to a government contract ***and for the benefit of the Government***." *Id.* at 1366. Crucially, the court would not have included the latter phrase had it applied Moderna's authorization-and-consent-only test. What is more, the court separately analyzed the "for the Government" and "authorization and consent" prongs of § 1498, confirming that each one must be satisfied before the Government can be held liable for a contractor's infringement. *Id.* at 1365-67. Moderna also cites *Pieczenik v. United States*, 2023 WL 5031507, at *2 (Fed. Cir. Aug. 8, 2023), but that decision says nothing about the "for the Government" prong. In *Piezcenik*, the court's conclusion rested on the lack of "factual allegations linking the accused use to any ***authorization and consent*** by the government," rather than on any conclusion about the "for the Government" prong. *Id.* Moderna points to *no case* where § 1498(a) applied simply because the

Government paid a private party to provide goods or services used by the general public.

Instead, Moderna claims there are no cases "examining 'benefit' as a factual matter where the contractor supplied the goods or services directly to the U.S. Government with the Government's express authorization and consent." Br. 12-13. Not so. In *Carrier Corp. v. United States*, 534 F.2d 244, 247 (Ct. Cl. 1976),[2] a contractor supplied trash removal services directly to the Government on a military base under a contract providing express authorization and consent. After examining the facts, the Court held that the infringement was not "for the Government" because it did not provide a benefit to the Government; instead, the infringement "had a usefulness only with respect to" the contractor. *Id.* But even were Moderna right about the lack of authority, it would be because, as far as Plaintiffs are aware, no one ever has invoked § 1498 in circumstances like these, so this Court was the first to reject (correctly) Moderna's novel and atextual reading.

b. Moderna has not established that the Government derived a direct benefit from the C-100 doses.

Moderna's effort to erase the "for the Government" prong transparently arises from its inability to show the purchase of vaccines for Americans was "for the Government," rather than merely benefiting the Government indirectly as a result of the benefits to the American public. Plaintiffs adduced substantial discovery from the Government, including data about the entities that received the C-100 doses and the testimony of Dr. Robert Johnson, an Operation Warp Speed leader designated to offer testimony in this matter by the Secretary of Health and Human Services ("HHS"). The C-100 contract itself is clear that the intended recipient of Moderna's vaccines was the American people, stating "that vaccine was to be developed to 'improve *patient care*,' thereby 'mitigating the impact of COVID-19 on *the nation and its people*.'" D.I. 64 at 3. And so it proved:

[2] The Federal Circuit adopted the prior holdings of its predecessor, the Court of Claims, as binding precedent. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982).

Data produced by HHS show that 98% of C-100 doses were distributed to the public, rather than the Government. ASOF ¶¶ 1-7; M. Ex. 63 ¶ 56. Most of these doses were distributed by non-federal entities. For example, doses were provided to state and local governments, pharmacies (like CVS), and private dialysis clinics. *Id*. Indeed, the Government's own testimony, ignored by Moderna despite its myopic focus on the Government's say-so, confirmed that these doses were ***not*** "for the federal government." Ex 32 (Johnson Tr.) 101:22-102:3 ("Q. But those doses, once they went to the jurisdictions, *weren't used for the federal government*; correct? A. Correct."), 103:16-104:10 (pharmacies), 106:20-107:20 (dialysis centers). The Government never physically possessed these doses, which Moderna and McKesson distributed. *Id.* at 167:4-12. Once it allocated doses to these channels (like pharmacies and local governments), the Government did not decide how the doses would be distributed within those channels. *Id.* at 168:11-169:15.

Remarkably, Moderna disregards all of this evidence and argues that Plaintiffs "fail[ed] to offer any evidence" that § 1498 does not apply. Br. 9. That is not only inaccurate, it reverses the burden of proof. It is Moderna's burden to demonstrate § 1498's applicability. *Toxgon*, 312 F.3d at 1383. And it is Moderna that failed to offer any evidence establishing § 1498 applies, other than citing the very contract provisions that Chief Judge Goldberg found lack clear language "establishing that the development of the vaccine was 'for the Government.'" D.I. 31 at 13.

Against this record, Moderna's theory that vaccines intended for the American public were "for the Government" cannot be reconciled with the meaning of § 1498. The statute's text, history, and interpretive case law all limit § 1498 to instances where the Government is a direct beneficiary, rather than benefiting indirectly through the American people. Starting with the plain English text, when the statute says an invention is "used or manufactured by or *for* the United States," it means that the Government itself directly benefits from the use or manufacture. That was true when

Congress passed § 1498; the word "for" was used to "[i]ntroduc[e] the intended recipient." *For*, A New English Dictionary on Historical Principles (1901) (as compiled in the Oxford English Dictionary (1st ed. 1933)); *For*, Webster's Int'l Dictionary of the English Language (1st ed. 1907) ("[T]he end or final cause with reference to which anything is, acts, serves, or is done.,"); *FastShip, LLC v. United States*, 892 F.3d 1298, 1303 (Fed. Cir. 2018) (using the same two dictionaries to interpret § 1498). Thus, while the Government facilitated the vaccination of many Americans, it was not the recipient or direct beneficiary of those doses—the doses were not ***for*** the Government.

That interpretation compelled by the text is consistent with the history and case law surrounding § 1498. Congress passed the provision during World War I, "to stimulate contractors to furnish what was needed for the war." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928); *Zoltek*, 672 F.3d at 1315 (explaining that § 1498 was passed to protect "the United States' procurement of important military matériel"). The genesis of § 1498(a)'s language was to ensure the availability of goods ***for the Government itself*** in war efforts. *See Coakwell v. United States*, 372 F.2d 508, 511 (Ct. Cl. 1967) (§ 1498 "enabl[es] the Government to purchase goods for the performance of its functions"). The statute had nothing to do with governmental efforts to procure goods or services for the public writ large. Indeed, "[e]ven where 'the government has an interest in [a] program generally, or funds or reimburses all or part of [its] costs,' the Government's interest is too remote 'for the purposes underlying § 1498.'" D.I. 31 at 9. Section 1498 is thus most commonly invoked in support of military procurement. *E.g.*, *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1573 (Fed. Cir. 1997) (eyewear for soldiers); *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 968 (C.D. Cal. 2019) (crystal sheets for fighter jet windows). In such cases, the benefit to the Government is clear and is exactly what Congress intended—"[t]he purpose of § 1498 dictates that its strongest protection should be extended to

contractors who sell military goods to the government." *Saint-Gobain*, 369 F. Supp. 3d at 976.

Although the question of Government benefit may require additional consideration outside of the military procurement context, it is only a straightforward analysis of whether the Government benefited directly, not a complicated quantitative analysis or factual examination. Moderna oddly accuses Plaintiffs of instead advancing a fact-intensive test. Br. 16. But it was Moderna who served opening expert reports attempting to quantify the benefits to the Government based on indirect downstream effects like hospitalization costs and tax revenue. *See* M. Ex. 30 (Rutherford); M. Ex. 31 (Vellturo). Plaintiffs simply offered rebuttal experts critiquing the transparent errors in Moderna's analysis. *See* M. Ex. 62 ¶¶ 17-22; M. Ex. 63 ¶¶ 24-28.

The flaw in Moderna's invocation of § 1498 is not the quantity of benefits but whom those benefits are ***for***. The law is clear that "[w]here benefits to the Government are merely an incidental effect of private conduct, they do not constitute 'use or manufacture for the Government' within the meaning of § 1498." *Sheridan v. United States*, 120 Fed. Cl. 127, 131 (2015). Crucially, courts have rejected §1498 defenses when the infringer produced goods or provided services for private parties, because the resulting benefits to the Government were "***too remote***," *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992) (payment for medical products used by Americans was not for the Government's benefit), "***indirect***," *Windsurfing Int'l, Inc. v. Ostermann*, 534 F. Supp. 581, 588 (S.D.N.Y. 1982) (use of a patented surfboard by U.S. Olympic team was not "for the government," even though "the United States has great interest in the running of the Olympics generally"), or a "***byproduct***" of infringement, *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998) (Government's receipt of a royalty from defendant's oil drilling using a patented drilling method did not make infringing use "for the Government").

Larson is squarely on point, as Chief Judge Goldberg found. D.I. 31 at 12 ("I find this case

more akin to *Larson* than *Advanced Software Design* or *Saint-Gobain Ceramics*."). COVID-19 vaccination directly benefited vaccine recipients, not the Government. "[M]edical care is provided for the benefit of the patient, not the government," D.I. 64 at 3 (quoting *Larson*, 26 Cl. Ct. at 369), even if the Government "funds or reimburses all or part of its costs." *Larson*, 26 Cl. Ct. at 369.

The beneficiary is the same whether the care is a splint or a vaccine. Moderna never even acknowledges Chief Judge Goldberg's reliance on *Larson*, and seeks to distinguish *Larson* based merely on the type of medical care, arguing vaccination had "effects far beyond individual recipients, including prevention of widespread severe infections of others across the nation and globally." Br. 15. But the Government is not the direct beneficiary of avoiding those infections either. As Moderna's expert admits, the direct benefits accrue to recipients—"those who received the vaccine were less likely to develop asymptomatic infection, symptomatic infection, and severe infection." M. Ex. 30 ¶ 71. The broader effects Moderna cites, from saving Government money on hospitalizations, to greater employment and tax revenue, are all ***byproducts*** of the direct benefit to the recipients and thus irrelevant. *See Riles*, 999 F. Supp. at 940. In any event, they are attenuated (tax receipts resulting from economic growth, which resulted from businesses re-opening, which resulted from greater immunity, Br. 16-17) and dubious (alleged cost savings looks only at immediate savings and not long-term budgetary effects, M. Ex. 62 ¶¶ 43-51). But that type of detailed analysis is ultimately unnecessary. Even accepting all of these benefits as true, they are indirect and incidental. The vaccines—and the direct benefits of the vaccines—were for the American public that received their protection, not the Government that paid for them.

c. Moderna's interpretation would massively expand Government interference with private property rights.

Moderna asks this Court to expand dramatically the executive branch's authority to shift infringement liability to the Government, without specific Congressional authorization. This

Court (D.I. 31 at 12-13) already noted the severe consequences of that approach, which would impermissibly deprive patent holders of their valuable rights by Government fiat:

> [T]o credit Moderna's argument based on the preamble language of the contract . . . could mean that every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense. This is particularly true in this case where the race to develop a COVID-19 vaccine may have occurred even in the absence of Government involvement and was simply expedited by the national effort to hasten the process.

Yet this remains Moderna's position. Its expert, Dr. Rutherford, advanced this broad view of Government benefit: "policies that improve the health, wealth and well-being of the general population also benefit the government, since the government is in fact for the people." M. Ex. 30 ¶ 33. Asked "what distinction … do you draw between society and the [U.S.] government," he replied, "None. What's good for the people is good for the government." Ex 56 (Tr.) 137:17-21.

The effects of Moderna's theory are not hypothetical. A political movement advocates using § 1498 "to circumvent" pharmaceutical patents. *E.g.*, Ex 38 (N.Y. Times Editorial); Ex 39 (Yale J. Art.). This view has found a footing with some legislators, who propose using § 1498 to force compulsory licensing "in the interim" before Congress "develop[s] and pass[es] drug pricing legislation." Ex 40 (Sen. Warren Ltr); Ex 41 (Sen. Sanders Ltr) ("HHS has the authority (under [§] 1498) to break the patent monopoly."). And since the Federal Government is "the largest purchaser of prescription drugs in the" U.S., M. Ex. 63 ¶ 30, the consequences of this theory for property rights and the public fisc are staggering. Grasping for a limiting principle, Moderna suggests in passing that direct purchases are different than Medicare reimbursement. Br. 14-15. But § 1498 "does not require that the government be party to any contract, but may apply to activities by 'any person, firm, or corporation' for the benefit of the government." *Advanced Software*, 583 F.3d at 1378. Moderna offers no basis to conclude that whether infringement is "for

the Government" turns on the particular funding method for the purchase. Its expert confirmed that its argument is not so limited: applying Moderna's reasoning would mean that sales under Medicare or Medicaid are also for the Government's benefit. Ex 56 (Rutherford Tr.) at 135:9-13 (agreeing that "benefits received under Medicare and Medicaid" are "benefits to the [U.S.] government"). Moderna's theory thus would bestow on the executive branch unfettered discretion to subvert exclusionary property rights (including rights to a jury trial and to seek injunctive relief and enhanced damages, *Return Mail, Inc. v. U.S. Postal Serv.*, 587 U.S. 618, 622, 634 (2019)), and allocate funds over a huge swath of the economy without Congressional action. Ex 40.

d. At most, only the limited set of doses used by federal agencies could be considered "for the Government."

The C-100 contract clearly was not for the Government's benefit—its purpose was to fund vaccine doses for Americans, and the HHS distribution data confirm that it did so. *Supra* at 6. However, even were the Court to decide the application of § 1498 at a per-dose level, the HHS data show that only about 3% of the C-100 doses went to federal agencies. ASOF ¶¶ 1-7; M. Ex. 63 ¶¶ 52-56, 56 n.61. For more than half of that 3%, the Government was simply a pass-through, with the doses used for vaccinations of the public, such as through health clinics operated by non-federal entities (but funded by the federal Health Resources and Services Administration), M. Ex. 63 ¶¶ 54-55. Most of the doses allocated to the Government do not even fall within the 3% assigned to agencies and instead were donated to foreign governments (81% of the "federal" allocation, and 16% of the overall C-100 doses, were donated). Ex 34 (Santoli Aff.). The direct beneficiaries of these foreign doses were the vaccine recipients in other countries. *Supra* at 8-9. These doses are even further removed from any direct Government benefit, and Moderna has no support for its argument that foreign doses were "for the Government," other than citations to White House press releases from a subsequent Administration. *See* M. Ex. 30 ¶ 85. Thus, even if

the Court divided the C-100 contract based on how each dose was used, the most that could be considered "for the Government" is 6.25 million doses—1.25% of the 500 million C-100 doses. M. Ex. 63 ¶ 56, 56 n.61); Ex 34 (Santoli Aff.); ASOF ¶¶ 1-7.

2. Section 1498 does not extend to *indirect* infringement.

Even if § 1498 applied (it does not), it cannot make taxpayers responsible for Moderna's indirect infringement, which separately entitles Plaintiffs to summary judgment on Moderna's defense, at least as to those claims. The waiver of sovereign immunity is limited to direct infringement—"the Government is not liable for its inducing infringement by others, for its conduct contributory to infringement of others, or for what, but for section 1498, would be contributory (rather than direct) infringement of its suppliers." *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980); *see also Gargoyles*, 113 F.3d at 1581 ("[T]he government has not waived sovereign immunity for collateral acts like inducement and contributory infringement.").

Plaintiffs alleged indirect infringement in the Complaint, D.I. 1 ¶¶ 90-91, 131-132, 155-156, 174-175, and during expert discovery, Ex 48 (Mitchell) ¶¶ 759-781. For example, Plaintiffs allege Moderna "intentionally encouraged doctors and other healthcare professionals to administer the COVID-19 vaccine" and for individuals to receive it, including through its packaging, instructions, and marketing. Ex 48 (Mitchell) ¶¶ 764-767. Moderna has been on notice that § 1498 cannot shield indirect infringement since (at least) the motion to dismiss briefing in early 2023. D.I. 59 at 7. Yet Moderna neither moved for summary judgment of non-infringement nor addressed Plaintiffs' assertion of indirect infringement in its § 1498 motion. The cases involving indirect infringement that Moderna cited in the motion to dismiss briefing, *see* D.I. 23 at 8-9 (citing *Astornet Techs. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277-78 (Fed. Cir. 2015); *Morpho Detection, Inc. v. Smiths Detection Inc.*, 2013 WL 5701522, at *4 (E.D. Va. Oct. 17, 2013)), both involved instances where the Government performed the underlying act of direct infringement. Not so here.

Moderna did not induce the Government, but the private healthcare providers at pharmacies and doctors' offices who administered the vaccine and thus committed direct infringement. Ex 48 (Mitchell) ¶ 765. Moderna cannot establish that its indirect infringement is subject to § 1498.

3. Moderna's fraudulent inducement of authorization-and-consent creates a dispute of fact precluding summary judgment for Moderna.

"[A] government contract is 'tainted from its inception by fraud' and is thus 'void ab initio,'" where "the contractor (a) obtained the contract by (b) knowingly (c) making a false statement." *Long Island Sav. Bank, FSB v. United States*, 503 F.3d 1234, 1246 (Fed. Cir. 2007). Here, the Government asked Moderna directly about its infringement of the very patent family asserted in this case. Moderna falsely responded that it did not infringe those patents (as shown by the same evidence that demonstrates its willful infringement), enabling Moderna to obtain contractual authorization and consent, which is thus void. Moreover, that clause was the basis for the Government's Statement of Interest that Moderna had authorization and consent. D.I. 49 at 8 ("The [C]-0100 Contract contains express 'authorization and consent' in the form of the well-established FAR clauses 52.227-1 and 52.227-1, Alternate I."). Moderna cannot use the fruit of its fraud to shift its liability to the Government. The evidence of Moderna's fraud creates a dispute of fact as to authorization and consent, precluding judgment in Moderna's favor as to § 1498.

a. Moderna's falsehood enabled it to obtain the contract (and authorization and consent).

On July 23, 2020, soon before the C-100 contract, the PTAB rejected Moderna's challenge to the '069 Lipid Composition Patent. *Moderna Therapeutics, Inc. v. Arbutus Biopharms Corp.*, 2020 WL 4237232 (P.T.A.B. July 23, 2020). Senior leadership at OWS, including its head, General Perna, were notified of the decision, Ex 73 (OWS Email), because the potential inclusion of an authorization and consent clause in the contract led the Government to follow this specific PTAB proceeding, Ex 32 (Johnson Tr.) 121:4-9. The day after the decision issued, an OWS officer

advised Moderna that as part of contract negotiations, it "should be prepared to discuss . . . the effect of Moderna's attempt to void the Arbutus Patent, if any." Ex 74 (OWS-Moderna Email).

Moderna responded that "the LNP formula used to manufacture mRAN-1273 [sic—mRNA-1273] is not covered by the Arbutus patent." Ex 74 (OWS-Moderna Email). There is significant evidence that the Government relied on this representation. Almost immediately after Moderna's representation, the Government held a meeting regarding the Moderna contract, which included a discussion of the PTAB decision. Ex 76 (Meeting Invite). Then on August 7—two days before executing the contract—OWS held a conference call on "IP rights" with Moderna, including its legal counsel. Ex 77 (Meeting Invite, Bennett Ex 34). The Government's witness, Dr. Johnson, testified that the Government did not engage in any independent analysis of Arbutus's patents beyond the assurance it received from Moderna. Ex 32 (Johnson Tr.) 23:14-24:21.

b. Moderna's representation was knowingly false.

Overwhelming evidence demonstrates that Moderna knew its vaccine infringes Plaintiffs' patents when it told the Government the opposite. Moderna's FDA submissions, Plaintiffs' independent testing and Moderna's own testing, all show clearly that Moderna infringes the Lipid Composition Patents. Ex 48 (Mitchell) ¶¶ 453-476, 497-502, 609-621. That infringement comes as no surprise to Moderna, which has long known its vaccine infringes, including when it represented otherwise to the Government in July 2020. *See* Ex 48 (Mitchell) ¶¶ 819-831.

The jury will hear considerable evidence of Moderna's willful infringement. There is no dispute that Moderna has known about Plaintiffs' patents, including their coverage of the 50% cationic lipid formulation, for many years. Ex 78 (Kramarczyk Tr.) at 60:4-8 ("At the time I understood that 50 mole percent cationic lipid was covered under a granted patent."); Ex 79 (Francis Tr.) at 40:3-41:9, 63:18-64:6. Yet Moderna decided to use that formulation as its "standard LNP" anyway. Ex 25 (Himansu Tr.) at 200:21-201:12; Ex 48 (Mitchell) ¶ 238. There

is even evidence it tried to hide that fact from Plaintiffs, like a 2013 email to Moderna CEO Stéphane Bancel that discussed removing details about the "delivery vehicle" formulation from a document before sending to Plaintiffs' predecessor, because, as a Moderna scientist remarked, "[t]his way we can ... leave them wondering if it is theirs." Ex 80 (MRNA-GEN-01759821).

Well aware it was practicing Plaintiffs' patents, Moderna sought a sublicense to the patents through another company, Acuitas. Ex 82 (Lawton) ¶ 1671. Acuitas's rights to the patents were disputed, and following a 2017 settlement, Moderna no longer could rely on Acuitas for a license to Plaintiffs' patents for most vaccines, including against COVID-19. *Id.* In the absence of a license, Moderna knew its products would infringe Plaintiffs' patents, and set internal goals to "[f]ix backward risk balance ... LNP/Abus," Ex 83 (2017 "Platform objectives"), and to "avoid licensing (intellectual property regarding 50 mole percent cationic lipid)," Ex 84 (2018 presentation) at -431. Crucially, Moderna knew what it needed to do to avoid infringing the patents. Moderna president Stephen Hoge wrote to his head of Drug Product Sciences that he would "like to reemphasize that there are ***incredibly strong business reasons*** why a composition with [redacted] is more attractive," and that he "would be willing to contemplate a delay to identify such a composition." Ex 85 (MRNA-GEN-02619870). After Moderna's experiments with [redacted] formulations failed repeatedly, Ex 48 (Mitchell) ¶ 313, it opted to use infringing formulations in its COVID-19 vaccine, making no changes beyond a "slight" adjustment to its target lipid content to try to [redacted] ***for IP purposes***." Ex 91 (2020 Specification Comm. Min.); Ex 48 (Mitchell) ¶ 463; *see infra* at 17.

Moderna also knew it was infringing based on its own test results. Moderna performed a fractionation study on its COVID-19 vaccine—the same test Plaintiffs performed in this case—which showed "infringing fractions having greater than 50 mol% ionizable lipid in each batch

tested." Ex 48 (Mitchell) ¶ 825. Indeed, Moderna refused to conduct any other experiments of that type because they could "pose uncomfortable questions" about "what we hope will soon be a commercial product." Ex 86 (Moderna Email). Moderna also covered up evidence that it was infringing. For example, a 2019 email ordered one scientist to remove references to the role of the MC3 lipid (which Moderna had used in conjunction with the patented formulations) from scientific presentations: "I know it is hard as a chemist but ***we have to fib a bit*** and not tell the whole structure story. The slides look great, ... but I think you need to take out the mc3 part of the story." Ex 88.

There is no indication that the Government has ever been aware of any of this evidence. As a result, there is a live factual dispute at to whether the Government would have provided its authorization and consent in the C-100 contract if it had known of Moderna's willful infringement.

c. Plaintiffs have standing to challenge the C-100 contract.

Moderna asks this Court to extinguish a portion of Plaintiffs' claim and constitutional right to a jury trial based on the C-100 contract. It cannot simultaneously avoid judicial scrutiny of that contract—effectively using it as both a sword and a shield. "Fairness demands that a third-party such as [Plaintiffs] be allowed to challenge the validity of a contract once a party to the contract makes it an issue in the case." *SmartSignal Corp. v. Expert Microsystems, Inc.*, 2006 WL 1343645, at *2 (N.D. Ill. May 12, 2006) (permitting plaintiff to challenge validity of contract defendant relied on for § 1498 defense). Indeed, the Federal Circuit specifically instructs that, in evaluating a § 1498 defense, the Court must make findings as to "precisely how the [contract] authorizes the government's consent to suit or authorizes [defendant] to use or manufacture the patented articles for the government." *Madey v. Duke Univ.*, 307 F.3d 1351, 1360 (Fed. Cir. 2002).

Moderna bears the burden to show authorization and consent, and Plaintiffs are entitled to negate that evidence—here, the authorization in a purportedly valid contract. That is consistent with other circumstances where a party must prove that a contract is valid. For example, plaintiffs

in tortious interference cases must establish the validity of the interfered-with contract, and the defendant—though not a party to that contract—is permitted to challenge that validity. *Park Lawn Corp. v. PlotBox Inc.*, 2021 WL 5038751, at *2 (D. Del. Oct. 29, 2021) (dismissing interference claim because "you can interfere with a void contract only as much as you can murder a ghost").

B. The Court Should Deny Summary Judgment of Prosecution History Estoppel.

The doctrine of equivalents (DOE) is a critical safeguard against "the unscrupulous copyist" who makes "unimportant and insubstantial changes … which, though adding nothing, would be enough to take the copied matter outside the claims." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950). "Few propositions of patent law have been so consistently sustained by the Supreme Court," *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1329 (Fed. Cir. 2019), and its application is particularly appropriate here.

As described above, Moderna knowingly used Plaintiffs' revolutionary LNP technology for years and infringes both literally and under DOE. *Supra* 14-16. It tried to invalidate asserted patents in failed IPRs, declined to take a license for its COVID vaccine, and (unsuccessfully) tried to design around the patents. Moderna argues here that potential infringers were not on notice that [redacted] could infringe, Br. 18, but its President Stephen Hoge knew precisely how Moderna could avoid infringement. In a pre-litigation email, he expressed his view "that there are incredibly strong business reasons why a composition with [redacted] ***lipid*** is more attractive." Ex 85 (MRNA-GEN-02619870) at -870. Moderna tried and failed to reach that [redacted] It opted instead for an "unimportant and insubstantial change[]," *Graver Tank*, 339 U.S. at 607—for example, target [redacted] just outside the literal 50-65% claim scope of most the Lipid Composition Patents, Ex 48 (Mitchell) ¶¶ 400, 436—that Moderna knew would yield infringing particles. Both Moderna's and Plaintiffs' testing confirmed literal infringement across all versions of Moderna's vaccine. *E.g.*,

id. ¶¶ 611-614, 649-652. Those same formulations also contain particles that are insubstantially different from the claimed inventions—and thus infringe under DOE. *Id.* ¶¶ 653-741. Moderna itself repeatedly told FDA as much to expedite approval. *E.g.*, Ex 92 (MRNA-GEN-01352552) at -554 (lipid content change did not "affect[] the product attributes"); Ex 93 (MRNA-GEN-00164205) at -207 ("minor adjustment[]" with no "detectable difference in immunogenicity").

Moderna seeks to escape the consequences of its actions by contending that, in prosecution, Plaintiffs disclaimed the accused equivalents (*i.e.*, compositions down to 45 mol % cationic lipid; up to 53 mol % non-cationic lipid; up to 3 mol % conjugated lipid). Moderna lost its amendment- and argument-based estoppel arguments during claim construction, and the Court should not afford Moderna a second bite at the apple. Regardless, Moderna's arguments remain meritless.

1. Amendment-based estoppel

Moderna contends that its already-rejected interpretation of the prosecution history means that the asserted equivalents fall within the scope of territory Plaintiffs surrendered by amending the claims to remove the word "about." Br. 19-26. That position cannot be squared with Chief Judge Goldberg's prior finding and the prosecution history record, which establish that Plaintiffs only disclaimed the "*broader ranges*," *i.e.*, +/- 10, 20, 30 mol %, of each lipid component.

a. The Court already rejected the basis for Moderna's argument.

During claim construction, Moderna argued the claims should be construed with numerical precision, precluding any deviations from the recited amounts. Per Moderna, "Plaintiffs gave up any variability when they deleted 'about' from the claims during prosecution." D.I. 170 at 15; *id.* at 17-19, 44. Plaintiffs urged that the "file history unambiguously establishes that the Examiner equated 'about' with '+/- 10, 20, 30 mol %,' [and] Plaintiffs amended the claims to obviate this reading." *Id.* at 37-38. Thus, Plaintiffs argued, they only disclaimed the broader ranges encompassed by the Examiner's definition of "about" (+/- 10, 20, 30 mol %), not everything up to

the edge of the recited ratios, as Moderna urged. The Court sided with Plaintiffs, D.I. 266 at 21:

> [T]he examiner believed that the term "comprising about" added before the mol % ranges "read on a broad range of amounts" and "could embrace an amount +/- 10, 20, 30 mol % of a lipid component." Thus, a claimed ranged of "about" 50-65 mol % could potentially encompass a range as small as 40-75 mol % and as large as 20-95 mol %. When Plaintiff removed the phrase "comprising about," ***it only clearly disclaimed these broader ranges*** … .

Moderna now recycles the same argument Chief Judge Goldberg rejected, this time to argue that Plaintiffs' alleged equivalents just outside of the claimed lipid ranges are not tangential to the amendment removing "about" from the claim. Although the ultimate legal issue presented at claim construction was different, the Court's prior interpretation of the amendment as "***only*** clearly disclaim[ing] these broader ranges"—i.e., +/- 10, 20, 30 mol %—is dispositive here too, because the equivalents are not within that "broader" scope. *Infra* 21-22. Moderna has provided no new evidence or basis to disturb the Court's prior ruling. *Bausch & Lomb Inc. v. SBH Holdings LLC*, 2025 WL 1005815, at *8-9 (D. Del. Apr. 3, 2025) (excluding expert's prosecution history estoppel analysis after rejecting the same argument during claim construction).

b. Moderna's argument is meritless.

Even were the Court to revisit its prior assessment of the prosecution history, Moderna's argument remains meritless. Moderna spends much of its brief arguing what Plaintiffs do not dispute: that the removal of "about" during prosecution was a narrowing amendment. Br. 19-22. The issue is the impact of that amendment. The amendment squarely meets one of the three *Festo* exceptions. Because Plaintiffs only disclaimed the broader ranges disclosed in the prior art (MacLachlan), and not narrower accused amounts ***not*** disclosed in the prior art, the reason for the amendment is "tangential" to the equivalents at issue, so estoppel cannot apply as a matter of law.

The tangentiality exception "asks whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Festo Corp. v. Shoketsu Kinzoku*

Kogyo Kabushiki Co., 344 F.3d 1359, 1369 (Fed. Cir. 2003). Moderna argues that because "both the reason for the amendment and the asserted equivalent relate to the concentration of the [lipid components], Plaintiffs cannot show[] that the rationale underlying the amendment was merely tangential to the accused equivalent." Br. 25. Precedent squarely rejects that very "bright-line rule" that "where the reason for the amendment and the equivalent in question both relate to the same claim element, the tangential exception does not apply." *Eli Lilly*, 933 F.3d at 1333. What matters is "the context in which [the amendment] was made, including the prior art that might have given rise to the amendment in the first place." *Id.* Amendments made to avoid prior art that *does not* disclose the alleged equivalent routinely meet the tangentiality exception. *Infra* 21-23.

Just as in claim construction, Moderna misconstrues the context of Plaintiffs' amendment. Moderna presents the file history as if MacLachlan disclosed a cationic lipid range up to 50 mol %, and Plaintiffs removed "about" from the claim to eliminate the overlap in that range. Br. 20. That is simply not the case. The reason for the amendment—as the Court found and Moderna ignores—was to address a specific legal doctrine that applies when "overlapping ranges" are present in the prior art. In particular, it "is well established that the disclosure of a genus," like a broad lipid range, "is not necessarily a disclosure of every species that is a member of that genus." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). Stated differently, just because a reference discloses a range of 2-60 mol % cationic lipid, as MacLachlan does, does not mean that it anticipates every point within that range, or even the end points. *UCB, Inc. v. Actavis Laby's*, 65 F.4th 679, 688 (Fed. Cir. 2023). Rather, "the prior art anticipates the claimed range only [] if it describes the claimed range with sufficient specificity such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges." *Id.* at 687. Thus, in *Atofina*, a prior art temperature range of 100-500°C did not describe

the claimed range of 330-450°C with sufficient specificity to anticipate, notwithstanding overlap between the reference's preferred 150-350°C range and the claimed range. 441 F.3d at 999-1000.

Both the Examiner and Plaintiffs addressed this law during prosecution. M. Ex. 75 at 6. The Examiner explicitly allowed the claims upon finding that without "about" in the claimed ranges—as he broadly interpreted it to include +/- 10, 20, 30 mol %— MacLachlan no longer disclosed the claimed ranges with "sufficient specificity." *Id.* The clearest evidence that this reasoning—and not disclaimer of lipid percentages just outside of the claimed ranges—was the reason for the amendment is that, both pre- and post-amendment, each of the four claimed lipid components overlap with MacLachlan's ranges identified by the Examiner (as illustrated for '069 Patent Claim 1), *see* D.I. 266 at 19:

Lipid Component	Original claim 1 (with "about")	Amended claim 1 (without "about")	MacLachlan's Ranges
Cationic Lipid	20 – 95 mol %	49.5 – 65.49 mol %	2–60, 5–50, 10–45, 30– 40, 30 mol %
Phospholipid/Non-Cationic	0 – 40 mol %	3.5 – 10.49 mol %	5–90 mol %
Cholesterol	0 – 70 mol %	29.5 – 40.49 mol%	20–55 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %	1–20 mol %

Had Plaintiffs amended to avoid prior art that "disclosed" or "taught the use" of the alleged equivalents, the tangentiality exception would not apply. *Bio-Rad Laby's, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1365-66 (Fed. Cir. 2020). But because the "only" reason for the amendment was to avoid MacLachlan's broad ranges stemming from the Examiner's construction of "about" to mean +/- 10, 20, or 30 mol %, D.I. 266 at 24, the rationale for the amendment bears no more than a tangential relation to the asserted equivalents. Moderna ignores this Court's interpretation and controlling law and assumes, without a scintilla of support or analysis, that MacLachlan discloses the accused equivalents. Br. 25. It decidedly does not. Crucially, MacLachlan discloses broad ranges and formulations containing 10, 15, 20, 30, and 40% cationic lipid, but not a single

formulation that falls within the literal scope of the claims or the asserted equivalents (*e.g.*, 45% or more cationic lipid). *E.g.*, M. Ex. 57 ¶¶ 247, 299, 318, 339, 341, 345, 348, 350, 352. For the same reason the Examiner found MacLachlan's broad range of 2-60% cationic lipid did not sufficiently disclose 50-65%, it does not disclose 45-65% either. *See Atofina*, 441 F.3d at 999.

Although " there is no hard-and-fast test for what is and what is not a tangential relation," *Eli Lilly*, 933 F.3d at 1333 (cleaned up), an amendment made to avoid prior art that *does not* teach the use of the alleged equivalent routinely is deemed tangential to the equivalent. In *Bio-Rad*, the claims were amended to recite a "non-fluorinated microchannel" to overcome prior art that taught "fluorinated" microchannels. 967 F.3d at 1360-61. Defendant 10X argued that prosecution history estoppel prevented Bio-Rad from accusing 10X's product—having a negligible quantity of fluorine—of infringing the "non-fluorinated" limitation. *Id.* at 1364. The Federal Circuit disagreed, explaining that "the reason for the amendment was to distinguish microchannels that reacted with carrier fluids," and the prior art "did not expressly disclose microchannels with non-reacting, negligible levels of fluorine, like in the accused equivalent." *Id.* at 1365-66. Because the prior art did not "teach the use" of the asserted equivalent, "the narrowing amendment can only be said to have a tangential relation to the equivalent." *Id.* at 1366.

In *Eli Lilly*, the Federal Circuit applied this same principle to claims to using antifolates in combination with an agent like vitamin B12. 933 F.3d at 1325. The claims initially were rejected over prior art disclosing a particular antifolate, methotrexate. *Id.* at 1326. Lilly obtained allowance upon narrowing the claims from "antifolate" to a specific "pemetrexed disodium" salt. *Id.* Hospira used a different salt—pemetrexed ditromethamine—and argued that the amendment estopped Lilly from asserting DOE. *Id.* at 1327. The court disagreed. That pemetrexed ditromethamine (the accused equivalent) was within "the territory between the original claim and the amended

claim" was of no moment. *Id.* at 1331. It likewise was immaterial that the amended claim was narrower than necessary or that Lilly knew of other pemetrexed salts. *Id.* The reason for the amendment was to avoid prior art that disclosed using an antifolate other than pemetrexed. *Id.* "Lilly's amendment, inartful though it might have been, was prudential in nature and did not need or intend to cede other pemetrexed salts." *Id.* at 1332. In short, the Federal Circuit routinely applies the tangentiality exception where, as here, the prior art did not disclose the accused equivalent. *E.g.*, *id.; Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1378 (Fed. Cir. 2008); *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 849 (Fed. Cir. 2006).

This principle and other case-specific facts distinguish Moderna's authorities. Br. 24-25. In *San Rocco*, the applicant amended its claim from "large portions of the β-globin locus control region" to "a 3.2-kb nucleotide fragment" to overcome an indefiniteness rejection. 2025 WL 1425341, at *3 (D. Del. May 16, 2025). The applicant stated that "[a]ny vector lacking the claimed 3.2-kb fragment … is excluded from the scope of the [claims]" and explained that changes to the 3.2-kb fragment "would alter a basic and novel property of the invention." *Id.* at *5. These express disclaimers doomed the tangentiality exception and readily distinguish *San Rocco* from this case.

Attempting to analogize to *San Rocco*, Moderna cites a statement from prosecution here that the 1:57 SNALP formulation presented "new and unexpected results" and a statement distinguishing prior art based on "the concentration of cationic lipid, among other elements." Br. 26. Moderna conveniently omits the cationic lipid ratios (and other lipid ratios) disclosed in the distinguished prior art—specifically "the 2:**30**, 2:**40**, and 10:**15** SNALP formulations as exemplified formulations containing the greatest amount of cationic lipid." M. Ex. 28 at 10; *see* M. Ex. 25 at 10; Counter-Statement of Facts ("CSOF") ¶ 64. No prior art MacLachlan formulation used [redacted] cationic lipid or the other equivalent lipid ratios. The claims thus were

distinguished from the far lower cationic lipid percentages in the prior art, D.I. 266 at 24, not all embodiments outside the claims, as in *San Rocco*.

Biagro W. Sales, Inc. v. Grow More, Inc., 423 F.3d 1296, 1306 (Fed. Cir. 2005), is equally inapposite. The claims, which recited buffered phosphorus fertilizers, were rejected over prior art disclosing a fertilizer that was buffered only when diluted. *Id.* at 1299, 1306. In response, the applicant added the limitation "wherein said phosphorus-containing acid … is present in an amount of about 30 to about 40 weight percent" and explained that the fertilizer must be concentrated to the specified range. *Id.* at 1305-06. The accused equivalent contained phosphorous compounds at a concentration of about 60%, "well outside the claimed range." *Id.* at 1300. The court did not apply the tangentiality exception because "both the reason for the amendment and the asserted equivalent relate to the concentration of the fertilizer." *Id.* at 1306.

Moderna cites this language to argue that because Plaintiffs' amendment and the asserted equivalent both relate to lipid component concentration, the tangentiality exception does not apply. Br. 25-26. But, as noted, the Federal Circuit later rejected this exact "bright-line rule." *Eli Lilly*, 933 F.3d at 1333. The *Biagro* "prosecution record [also] differ[s]" from the one here. *See id.* During prosecution, Biagro was silent as to the reason for the upper concentration amendment and thus could not show that the reason was tangential to the accused equivalent. 423 F.3d at 1306. Here, Plaintiffs' amendment objectively was intended to address the Examiner's construction of "about"—+/- 10, 20, or 30 mol %—and MacLachlan's broad disclosures. A formulation with 45 mol% cationic lipid (and the respective mol% conjugated lipid or non-cationic lipid) bears no more than a tangential relation to the reason for amendment, so estoppel cannot apply as a matter of law.

2. Argument-based estoppel

Moderna also contends that argument-based estoppel bars DOE for the "cationic lipid" limitation. Br. 26. "To invoke argument-based estoppel, . . . the prosecution history must evince

a clear and unmistakable surrender of subject matter." *Conoco, Inc. v. Energy & Env't Int'l, L.C.*, 460 F.3d 1349, 1364 (Fed. Cir. 2006). Again regurgitating arguments that the Court rejected, Moderna comes nowhere close to satisfying this exacting standard.

a. The Court previously rejected Moderna's argument.

During claim construction, Moderna asserted that the '378 patent requires at least 50 mol % cationic lipid, though the claims do not recite it. Moderna argued that Plaintiffs "made a clear and unmistakable disclaimer" of "particles with less than 50 mol % cationic lipid during prosecution," relying on the very prosecution and IPR statements it now cites. D.I. 170 at 52-53, 61. The Court disagreed: "Moderna relies heavily on the prosecution history to argue that Plaintiffs made a clear and unmistakable disclaimer of [LNPs] with less than 50% cationic lipid," D.I. 266 at 28, but "Moderna has not made [that] showing[]." *Id*. at 31. Moderna cannot challenge that ruling. *LoganTree LP v. Fossil Group, Inc.*, 2024 WL 5333951, at *2 (D. Del. Mar. 20, 2024).

b. Moderna's argument is meritless.

As before, Moderna relies on statements concerning the "new and unexpected results" of the 1:57 SNALP (57 mol % cationic lipid) formulation and the advantages imparted by increased amounts of cationic lipid. Br. 27-28. From these, Moderna concludes that "Plaintiffs clearly and unmistakably tied their claimed invention to formulations with high concentrations of cationic lipid—specifically to a formulation with 57 mol % cationic lipid." Br. 27. Even if true, the legally salient question is high ***compared to what***? *Abbott Laby's v. TorPharm, Inc.*, 300 F.3d 1367, 1372 (Fed. Cir. 2002) ("prosecution history inquiry asks not what words the patentee discarded, but what subject matter the patentee relinquished or disclaimed"). Moderna cites no evidence that Plaintiffs unmistakably restricted an "increased" or "higher" concentration of cationic lipid specifically to 50 mol % or more. On the contrary, Plaintiffs distinguished the invention from prior art disclosures of ***40 mol % cationic lipid*** or less. M. Ex. 72 at 10 ("1:57 SNALP formulations

were substantially more effective ... compared to" the "***2:40 SNALP***."); *id.* at 10 (same for "***2:30 SNALP***"); M. Ex. 75 at 10 (arguing "unexpectedly superior advantages over ... formulations containing" "***30 mol %, 40 mol %, and 15 mol % cationic lipid***."); Ex 90 (IPR2019-554, Paper 7 at 13); Ex 94 (IPR2018-739, Paper 12 at 6-7).

These statements are a far cry from those in Moderna's cited cases, Br. 27-28, where the applicants disclaimed the accused equivalent in question with far more specificity than the present record. *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1160 (Fed. Cir. 2019) (distinguishing reference as not teaching "particular combinations" recited in claims); *San Rocco*, 2025 WL 1425341, at *7 ("[T]he applicant emphasized ***eight times*** that the claimed invention is 3.2 kb."). This case is much more analogous to *Conoco*, 460 F.3d at 1364, where the applicant's explanation of "the criticalities of using fatty acid wax" over specific species in the prior art, "metal stearates," was not "a clear surrender of *all* fatty acid wax equivalents." There is no "clear and unmistakable surrender" of formulations with less than 50 mol % cationic lipid.

C. The Court Should Grant Summary Judgment of No Indefiniteness.

Moderna bears a clear and convincing burden to prove indefiniteness. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017). A claim is indefinite only if, when "read in light of the specification" and "prosecution history," it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Here, the *scope* of the asserted claims is undisputed. Moderna nonetheless asserts indefiniteness based on its expert's opinion that it is impossible to determine whether a composition falls within that scope. That is legally irrelevant: "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331,

1340-41 (Fed. Cir. 2005). Moderna can dispute infringement at trial by arguing (wrongly) that it is impossible to determine whether its vaccine falls within the scope of the claims. But Moderna cannot repurpose its *non-infringement* arguments as *indefiniteness* attacks. Moderna's remaining arguments are unsupported and conclusory, rendering summary judgment for Plaintiffs proper.

Alternatively, even were Moderna's arguments relevant, factual disputes plainly preclude summary judgment for Moderna. Moderna ignores the extensive evidence Plaintiffs advanced that a POSA readily could determine whether a formulation meets the '651 patent asserted claims.

1. The Court should grant summary judgment for Plaintiffs on Moderna's Lipid Composition indefiniteness arguments.

a. The scope of the Lipid Composition claims is unambiguous.

There is no dispute as to the bounds of the Lipid Composition Patents. The claims recite a "nucleic acid-lipid particle" and undisputedly require at least a *single* particle with the required components. The PTAB so recognized, construing "nucleic acid-lipid particle" to be "*a particle* that comprises a nucleic acid and lipids, in which the nucleic acid may be encapsulated in the lipid portion of the particle." *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, 2019 Pat. App. LEXIS 13612, at *13 (P.T.A.B. Sept. 11, 2019). Moderna adopted that construction as "based upon express disclosures in the specification," Ex 43 ('069 IPR Pet.) at 23, and had no difficulty applying it to the prior art, *id.* at 50-51. Nor did Moderna's experts here contest that the claims plainly encompass "a . . . particle" with the claimed elements. Ex 47 (Murthy) ¶¶ 1209-1211; Ex 45 (Prud'homme Reply) ¶¶ 148, 150; Ex 46 (Prud'homme Tr.) 161:5-11. Because its experts identify no ambiguity in claim *scope*, the inquiry ends. *SmithKline*, 403 F.3d at 1341.

Moderna's expert instead opines that it is "impossible to *measure*" the composition of individual LNPs. Ex 44 (Prud'homme) ¶ 229. His opinion—that claims "can be found indefinite if a POSA cannot determine whether a given composition falls inside or outside of the claims," Ex

45 (Prud'homme Reply) ¶ 150—is wrong: the "test for indefiniteness does *not* depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement." *SmithKline*, 403 F.3d at 1340-41. Construing the claim "to cover undetectable trace amounts" of a compound, the *SmithKline* court rejected the indefiniteness concern "that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound," as it "miss[ed] the proper purpose of the definiteness requirement." *Id.* "The scope of this claim is clear; the infringement of the [] product is not." *Id.* at 1341.

The law is clear: Dr. Prud'homme's opinions about the difficulty of assessing infringement are irrelevant to definiteness. *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1290 (Fed. Cir. 2023) ("disputes over infringement do not make a patent claim indefinite"); *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1346 (Fed. Cir. 2010) ("The difficulty or complexity of the infringement analysis does not necessarily speak to whether a claim is definite or not."); *Talecris Biotherapeutics, Inc. v. Baxter Int'l Inc.*, 510 F. Supp. 2d 356, 362-363 (D. Del. 2007) (whether claims "are indefinite ultimately amounted to the question of whether [POSA] would know what it means—not when or how it is determined"); *Confluent Surgical, Inc. v. HyperBranch Med. Tech., Inc.*, 2019 WL 2897701 at *8 n. 10 (D. Del. July 5, 2019) (argument that "patents provide no principled way to conclude whether" device infringes is irrelevant to definiteness).

b. Moderna's other arguments do not raise a material dispute.

Dr. Prud'homme makes two additional arguments, both insufficient to avoid summary judgment. ***First***, he asserts that different measurement techniques "may" produce different lipid composition data. Ex 44 (Prud'homme) ¶ 231. But "the mere possibility of different results from different measurement techniques" cannot render a claim indefinite. *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1366-67 (Fed. Cir. 2014). The "method of measurement" must "in fact [be] outcome-determinative in the infringement analysis" to establish indefiniteness. *Id.*

at 1367 n.4. Evidence of outcome-determinative differences is required; conclusory statements are insufficient. *BASF*, 875 F.3d at 1366 (reversing indefiniteness judgment); *Janssen Pharm., Inc. v. Teva Pharm. USA, Inc*. 97 F.4th 915, 937 (Fed. Cir. 2024) (challenger "did not present evidence that different measurement techniques would typically yield different [] measurements"); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Lupin Atlantis Holdings SA*, 2019 WL 4222673, at *4-5 (D. Del. Sept. 5, 2019) (claims definite because expert "sp[oke] only in generalities" and failed "to provide evidence that the different methods . . . would, in fact, produce different results").

Moderna failed to present evidence sufficient to meet this standard. LNP compositions, like Moderna's vaccine, contain numerous particles that vary across many dimensions, including lipid composition. Researchers have developed techniques to separate—or "fractionate"—the composition without modifying the particles. The properties of those fractions can then be tested. Moderna and others long have used these methods routinely. Ex 47 (Murthy) ¶ 1217.

Dr. Prud'homme argued that different fractionation techniques "may" yield "different results." Ex 44 (Prud'homme) ¶ 231. But he did not provide any evidence for this speculation, much less any data demonstrating outcome-determinative differences. *Takeda*, 743 F.3d at 1366-67. That evidentiary gap remained after Plaintiffs' expert identified it. Ex 47 (Murthy) ¶ 1219; Ex 45 (Prud'homme Reply) ¶ 156. That alone dooms Moderna's indefiniteness defense. But the evidence demonstrates that different fractionation methods *consistently show infringement*. Before this litigation, Moderna fractionated three vaccine lots, and each lot contained infringing fractions. Ex 48 (Mitchell) ¶ 613. Plaintiffs' experts also conducted fractionation studies, and—despite using a technique that differed from Moderna's—found that each tested vaccine lot (67 of 67) infringed asserted claims. *Id.* ¶¶ 650-651. Moderna did not advance testing of its own, and its speculation about hypothetical inconsistent results is insufficient to create a triable issue of fact.

Second, Dr. Prud'homme speculates that "ephemeral" in-process particles that "may or may not exist for some infinitesimally short" time are "likely to [yield] different results" each time they are tested. Ex 44 (Prud'homme) ¶ 233. Those particles (to the extent they exist) are not accused of infringement. Rather, Plaintiffs assert that (in addition to the final product) an intermediate composition that Moderna manufactures infringes. Ex 48 (Mitchell) ¶¶ 615-617. Dr. Prud'homme cites no evidence that particles in that composition are "ephemeral," or that measurements of any hypothetical "ephemeral" particles would yield different infringement results. Ex 47 (Murthy) ¶ 1220; Ex 44 (Prud'homme) ¶ 233. As such, Moderna cannot meet its burden, and summary judgment for Plaintiffs is proper. *Takeda*, 743 F.3d at 1366-67.

2. The Court should grant summary judgment for Plaintiffs on Moderna's "fully encapsulated" indefiniteness arguments.

Having convinced the Court to construe "fully encapsulated" as it urged, Moderna now asserts that *its own construction* is so inscrutable as to render the '651 patent claims indefinite. The construction, however, leaves no ambiguity about claim scope, and Moderna identifies none. Moderna again focuses on measurement—this time, of "partially" encapsulated mRNA—that is legally irrelevant because it goes (at most) to infringement. Its other argument—that different encapsulation measurements could produce different results—again lacks evidentiary support.

a. The scope of the '651 patent claims is unambiguous.

Moderna argues that the '651 patent claim term requiring a lipid vesicle formulation "wherein at least 70% of the mRNA . . . is fully encapsulated" in the lipid vesicles is indefinite.

As the Court's claim construction opinion explained, "[t]here is no dispute that" mRNA strands entirely contained inside the lipid vesicles "are 'fully encapsulated' inside the lipid vesicle" and strands entirely outside the vesicles "are not 'fully encapsulated.'" D.I. 266 at 32-33. The parties' only dispute pertained to whether a hypothetical mRNA strand that is "part-in-part-out"

of a particle would (for the part inside) fall within the claims' scope. *Id.* at 33. Moderna urged that such a strand, in its entirety, would count "as 'partially encapsulated' and therefore not 'fully encapsulated' as the claim requires." *Id.* The Court sided with Moderna. *Id.* at 37.

The Court resolved any possible ambiguity about the *scope* of the claims. It held that mRNA strands "fully contained inside the vesicle" fall within the claims, *id*. at 36, whereas strands that are "part-in-part-out" *or* unencapsulated do not. That decision is dispositive. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005) ("court's constructions" "showed that [claim] contained no material ambiguities, and therefore was not invalid for indefiniteness").

Flouting the Court's decision, Moderna now asserts that its "experts offered unrebutted testimony that 'fully encapsulated' ha[s] no defined meaning," citing conclusory deposition excerpts. Br. 30. "Conclusory expert assertions cannot raise triable issues of material fact on summary judgment." *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 941 (Fed. Cir. 2013). Those experts also did *not* identify uncertainty about the scope of the term, for example, by citing scenarios where it would be unclear if mRNA was "fully encapsulated." CSOF ¶¶ 131-132. Nor could they have, in view of the Court's delineation of what is fully encapsulated. Ex 47 (Murthy) ¶ 518. Indeed, Dr. Prud'homme confirmed his understanding of the claims' scope, as he "agree[d] with the Court that a 'POSITA would only count those strands that are fully contained inside the vesicle.'" Ex 45 (Prud'homme Reply) ¶ 46 n.4. Moderna's puzzling assertion that there is no accepted meaning of full encapsulation is particularly egregious given that Dr. Prud'homme's own patent uses that term, which he understood. Ex 49 (Prud'homme Ex 20); Ex 46 (Prud'homme Tr.) 215:14-219:11; *BASF*, 875 F.3d at 1368 (no indefiniteness where experts agreed on scope).

Unable to dispute the *scope* of the claim terms, Dr. Prud'homme again argues that the POSA could not *measure* infringement, largely due to uncertainty about measuring "partially"

encapsulated mRNA. Ex 44 (Prud'homme) ¶ 128; Ex 45 (Prud'homme Reply) ¶ 46 n.4. Those irrelevant opinions are bereft of factual support. Moderna's own witnesses testified that they never had seen evidence that partially encapsulated mRNA exists in the formulations at issue (*e.g.*, LNPs), Ex 46 (Prud'homme Tr.) at 189:14-191:9, Ex 95 (Schariter Tr.) at 162:8-12, rendering non-sensical Moderna's argument that such mRNA could significantly affect the encapsulation measurements in such systems, *Takeda*, 743 F.3d at 1366-67 ("mere possibilit[ies]" are insufficient to establish indefiniteness). Regardless, those opinions (at most) go to infringement, not definiteness, and cannot raise a material fact dispute. *Supra* II.C.1.a; *SmithKline*, 403 F.3d at 1341.

b. Moderna's other arguments do not raise a material dispute.

Moderna also argues that the claims of the '651 patent are indefinite because different methods of measuring encapsulation may yield different results. Br. 33-35. Moderna, however, has not proffered "clear and convincing evidence that the method of measurement is in fact outcome-determinative in the infringement analysis." *Takeda*, 743 F.3d at 1367 n.4.

Moderna contends that the patent does not describe a method for measuring encapsulation, Br. 34, but "there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo-Surgery, Inc. v. Covidien, Inc*., 796 F.3d 1312, 1319 (Fed. Cir. 2015). A "claim is not indefinite if a [POSA] would know how to utilize a *standard* measurement method . . . to make the necessary measurement," *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1376 (Fed. Cir. 2017); *compare Dow Chem. Co. v. Nova Chems. Corp*., 803 F.3d 620, 634 (Fed. Cir. 2015) (no evidence that a measurement technique was standard or preferred). Dr. Prud'homme does not dispute that dye-exclusion was the standard technique for measuring encapsulation. Ex 45 (Prud'homme Reply) ¶ 92; Ex 47 (Murthy) ¶¶ 549, 553-555.

The only evidence Moderna cites, Blenke, is inapt. Br. 34-35. ***First***, Moderna did not show that the assays in that 2018 article reflect the state of the art for measuring encapsulation at

the 2002 priority date, and Blenke itself highlights problems with the non-dye-exclusion assays. Ex 47 (Murthy) ¶ 562. Differences resulting from aberrant, non-standard testing cannot establish indefiniteness. *Janssen*, 97 F.4th at 937. ***Second***, Blenke does not measure mRNA (as claimed), and it attributes the variance observed to the shorter nucleic acid used. Ex 47 (Murthy) ¶ 558. Dr. Prud'homme agreed. Ex 45 (Prud'homme Reply) ¶ 63. Blenke thus cannot show differences that are "outcome-determinative *in the infringement analysis*." *Takeda*, 743 F.3d at 1367 n.4. ***Third***, Moderna mischaracterizes Blenke. Its expert did not dispute that the figure Moderna cites (Figure 4), Br. 34, does not report encapsulation, Ex 45 (Prud'homme Reply) ¶ 64. And Moderna does not contend that Blenke's actual encapsulation data (in Table 2)—even using its non-standard assays—demonstrate outcome-determinative differences for "the scope of claim 1." Br. 34.

The Court's claim construction left no ambiguity about the scope of the '651 claims. None of Moderna's arguments call that scope into question. Summary judgment for Plaintiffs is proper.

3. At the very least, the Court should deny Moderna's motion for summary judgment of indefiniteness of the '651 patent.

Moderna asserts that "the patent provides no guidance as to the difference between 'fully' and 'partially' encapsulated," and that "there is no accepted definition in the field for 'fully' or 'partially' encapsulated." Br. 30. The Court's claim construction Order resolved any possible ambiguity. *Supra* II.C.2.a. In any event, Plaintiffs' expert explained at length how the POSA understood those terms, Ex 47 (Murthy) ¶¶ 513-519, in testimony Moderna ignores. For example, Dr. Murthy testified that the POSA would understand "'full encapsulation' as used in the '651 patent" to refer to nucleic acid that is fully "contained inside the lipid vesicles such as in a system akin to lipid vesicles which have a 'lipid bilayer' ... encapsulating an aqueous interior," *id.*¶ 513, citing the patent, file history, and prior art, *id.* ¶¶ 512-518. Dr. Murthy pointed out that Moderna's scientists used and understood the term "fully encapsulated," as demonstrated in both internal

discussions and in a public statement by Moderna's former CSO, wherein she described Moderna's "fully encapsulated" mRNA LNPs as having "this beautiful lipid bio-layer around the outside." *Id.* ¶¶ 502, 514. Moderna's argument is particularly untenable given its expert's use of "fully" and "partially" encapsulated in his own patent. *Supra* II.C.2.a; Ex 46 (Prud'homme Tr.) at 219:3-11.

Moderna argues that the POSA would be uncertain as to what "partially" encapsulated includes and how to measure it, citing Plaintiffs' witnesses' testimony. Br. 30-32. ***First***, Moderna incorrectly assumes that measuring *partially* encapsulated mRNA is required; under the Court's construction, the numerical limitation is *only* to *fully* encapsulated mRNA. Moderna's arguments relate (at most) to non-infringement, not indefiniteness, *supra* II.C.2.a, but regardless, Dr. Murthy explained that once one measures fully encapsulated mRNA, whether the remainder is partially encapsulated or unencapsulated is irrelevant to infringement. Ex 47 (Murthy) ¶¶ 519-520.

Second, contrary to Moderna's position, Br. 32, 34,[3] Plaintiffs' expert testified that dye-exclusion and confirmatory techniques (*e.g.*, electron microscopy) can measure fully encapsulated mRNA and "differentiate" it from (hypothetical) partially encapsulated mRNA. *E.g.*, Ex 47 (Murthy) ¶¶ 532, 535, 538-539 (citing Moderna confirming mRNA was "fully encapsulated" versus "bound to the LNP surface"). Dr. Murthy also explained that there are "fully-encapsulated composition[s] (*e.g.*, [] an LNP)" and "composition[s] that do[] not exhibit full encapsulation (*e.g.*, a lipoplex)," which can be analytically distinguished. *Id.* ¶¶ 510-511, 574. Moderna argues that Plaintiffs' reliance on "encapsulation efficiency" measurements (*i.e.*, dye-exclusion) contravenes the *Markman* Order. Br. 33. That is incorrect, as Plaintiffs' experts cite techniques that can (and did) confirm lack of partial encapsulation in fully encapsulated systems (*e.g.*, LNPs). Ex 47

[3] That dye-exclusion assays measure encapsulation "indirectly," Br. 34, is irrelevant, as there is no dispute that they were the standard assay for assessing encapsulated mRNA.

(Murthy) ¶¶ 531-538. The Court did *not* find dye-exclusion irrelevant but merely explained that encapsulation efficiency "*may* be broader than" the claims. D.I. 266 at 37 n.13.

Third, Moderna ignores Plaintiffs' evidence that, in formulations capable of achieving the claimed encapsulation percentages (like LNPs), there will be no partially encapsulated mRNA. Ex 47 (Murthy) ¶¶ 503-506, 531-540, 581-583. Despite bearing the burden of proof, Moderna cites no evidence of partial encapsulation existing in *any* formulation within the claim scope (so it need not be measured), and its witnesses testified that they had never seen such mRNA. *Id.* ¶ 538.

Fourth, Moderna ignores Dr. Murthy's testimony about the cited deposition excerpts, including that (1) many witnesses were not testifying about their understanding in the context of the patent, or only worked with fully encapsulated systems, rendering their testimony about "partial" encapsulation irrelevant; (2) the witnesses *were* able to explain what "fully encapsulated" meant; and (3) the witnesses consistently described how to measure fully encapsulated mRNA and distinguish it from unencapsulated and partially encapsulated mRNA (if any). *Id.* ¶¶ 521-534.

Finally, Moderna argues that different tests yield different results. Moderna's article (Blenke) cannot create a triable issue of fact. *Supra* II.C.2.b. Were the Court to find otherwise, there are disputes about (1) whether the POSA would have used Blenke's methods, *Presidio*, 875 F.3d at 1376; and (2) whether Blenke's data show that different assays yield relevant, outcome-determinative differences, *Takeda*, 743 F.3d at 1366-67, particularly in view of Moderna's own consistent mRNA encapsulation data across different assays. Ex 47 (Murthy) ¶¶ 532, 563.

In short, there is, at least, a genuine dispute of material fact as to whether the claim language provides "reasonable certainty" about the "scope of the invention." *Nautilus*, 572 U.S. at 901.

III. CONCLUSION

The Court should deny Moderna's motion and grant Plaintiffs' cross-motions.

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Dated: August 29, 2025

CERTIFICATE OF SERVICE

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